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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/285,559 04/02/99 HECHEL

D 3216/75036

EXAMINER

QM22/0424

ART UNIT	PAPER NUMBER
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WELSH & KATZ
120 SOUTH RIVERSIDE PLAZA
22ND FLOOR
CHICAGO IL 60606

3737

DATE MAILED:

04/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/285,559

Applicant(s)

HECHEL ET AL.

Examiner

Runa S. Qaderi

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claims 1-7 claims 1 and 4 are rejected as being incomplete. The preamble claims an apparatus for applying ultrasound treatment while the body of the claims is directed towards a means adapted to be disposed on the body for providing a color change at a predetermined temperature. There is no ultrasound apparatus or treatment positively claimed in the body of the claims. The body of the claims is inconsistent with the preamble.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Chervitz.

In regard to claim 1 Chervitz discloses a thermochromatic strip comprising an adhesive visual indicator that changes color in response to temperature and is adapted to be disposed on the body portion, column 2, lines 4-17. The patent further teaches that the color spectrum of each liquid crystal indicator are responsive to a different specific temperature range, and the liquid crystal indicator being invisible at temperatures below the threshold temperature. In other words each liquid crystal indicator changes color only at this threshold or predetermined temperature, each indicator having a specific temperature range, column 2 lines 4-17. In addition the adhesive visual indicator of Chervitz is capable of being used with an ultrasound treatment because it is adapted to be disposed on the body to provide color change due to tissue temperature change.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the

differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chervitz.

In regard to claims 4 and 5 Chervitz discloses a thermochromatic strip comprising a visual indicator with an adhesive backing, and comprising of a plastic sandwich, colored backing, and displaying numeric characters. Chervitz teaches a visual indicator adapted to be disposed on the body that changes color and displaying numeric characters at the threshold temperature of the specific temperature range of the indicator. It would have been obvious for a person of ordinary skill in the art to substitute alphanumeric characters for numeric characters. Chervitz discloses a means for indicating when the threshold or predetermined temperature has been reached by displaying a color change and using characters. Therefore the characters could either be numeric or alphanumeric and in addition any message could be displayed using the alphanumeric characters.

4. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chervitz in view of Behnke et al.

In regard to claim 18 Chervitz teaches a thermochromatic strip that changes color and displays numerical characters at the threshold temperature. Chervitz does not teach the thermochromatic strip further comprising a tab color-coded with the threshold or predetermined

temperature. Behnke et al. teaches an analyte test strip that displays color changes to indicate results. A color comparison standard that is attached to the testing device for the quantitative evaluation of the degree of change in color, column 11 lines 9-11. It would have been obvious for a person of ordinary skill in the art to further comprise the thermochromatic strip with a color comparison tab to easily observe and compare the necessary color change at the predetermined temperature.

5. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watmough et al. in view of Chervitz.

In regard to claims 1-11 Watmough et al. disclose a method of applying ultrasound treatment wherein a temperature sensing visual indicator is in contact with treated tissue, wherein temperature of the skin is indicated by color changes, column 3 lines 21-23 and 30-33. In addition Watmough et al. disclose that frequency of the ultrasound is altered to alter depth and temperature distribution, column 3 lines 37-44. In regard to claim 11 Watmough et al. disclose a computer simulation for determining skin temperature, ultrasound absorption, thermal conduction, and different power settings of the transducer on the temperature distribution inside the tissue during local hyperthermia.

Watmough et al. differs from the claimed invention in that a securing mechanism via an adhesive backing is not addressed. Other features of the strip that are not addressed in Warmough et al. include the strip further comprising of a plastic sandwich, colored background, and character display. Also Watmough

et al. does not teach a color change at a predetermined or threshold temperature.

Chervitz discloses a visual indicator with an adhesive backing, and comprising of a plastic sandwich, colored backing, and displaying numeric characters indicative of temperature change. Chervitz teaches a visual indicator adapted to be disposed on the body that changes color and displays characters at the threshold temperature of the specific temperature range of the crystal indicator. See abstract, column 1 lines 14-17, and column 2 lines 4-9.

It would have been obvious at the time the invention was made to a person of ordinary skill in the art to determine an average depth of penetration of the ultrasound for the selected frequency, column 5 lines 13-16. Average is construed to mean typical or normal in this claim. Warmough et al. teaches a method that is applicable for predicting effected tissue characteristics due to ultrasound treatment. It would have been obvious to a person of ordinary skill in the art to use the temperature-detecting patch of Chervitz because it provides means for monitoring the ultrasound treatment via detecting when threshold temperature has been reached. Also it would have been obvious for a person of ordinary skill in the art to substitute alphanumeric characters for numeric character. Chervitz already discloses a means for displaying a temperature change using characters. Therefore the characters could either be numeric or alphanumeric and in addition any message could be displayed using the alphanumeric characters. Further it would have been obvious to indicate a visual

change only at a predetermined temperature in order to monitor ultrasound treatment.

6. Claims 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watmough et al. in view of Chervitz as applied to claims 1-11 above, and further in view of Cohen.

In regard to claims 12-17 Watmough et al. in view of Chervitz does not teach a thermochromatic strip that provides an opacity change when a dosage limit of the ultrasound treatment has been reached. Cohen teaches a thermographic or liquid crystal material with an adhesive backing provided in the front side of a pacifier flange that displays a change in color or opacity at or above a predetermined temperature, column 1 and 2. It would have been obvious to indicate an opacity change only at a predetermined temperature in order to monitor ultrasound treatment because it is an alternative means of a visual indication.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Runa S. Qaderi whose telephone number is (703) 308-8155. The examiner can normally be reached on Mon-Fri 7:00-3:30.

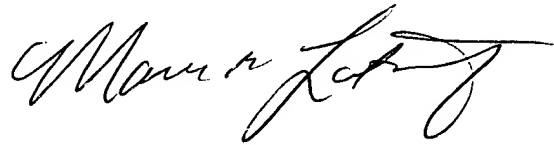
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on (703) 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

RSD

April 17, 2001



Marvin M. Lateef
Supervisory Patent Examiner
Group 3700